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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,937	09/21/2006	Kalman Hideg	67789-485	6143

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DAVIS WRIGHT TREMAINE LLP  
865 FIGUEROA STREET  
SUITE 2400  
LOS ANGELES, CA 90017-2566

EXAMINER
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CHU, YONG LIANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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08/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/553,937

Applicant(s)

HIDEG ET AL.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-28,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 26-28,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☒ Claim(s) 14-26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/13/2007</u> . | 6) <input type="checkbox"/> Other: _____   |

## **DETAILED ACTION**

Claims 14-28, and 33-34 are pending in the instant application.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement, filed on 07/13/2007, has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

### ***Priority***

This application is a 371 of PCT/HU04/00043 filed on 04/27/2004, and claims the benefit of Hungary Patent Application P0301154 filed in English on 04/28/2003 under 35 USC 119(a-d). The condition is met, and the priority is recognized.

### ***Response to Lack of Unity***

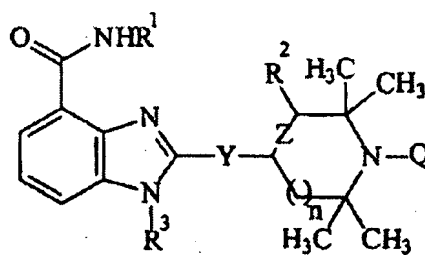
Applicants' election with traverse of Group II (claims 14-28 (in part)) and elected species of Compound 19 at page 24 of the Specification during the telephonic interview with Applicant's representative Seth D. Levy on 08/14/2007 is acknowledged. The original election of Group I on 06/26/2007 does not cover the elected species. Applicant's traversal for search and examining Group X has been considered, but not persuasive. The Group X is subject to rejoin only when the product claims are allowable. Accordingly, the restriction requirement is appropriate, and is maintained.

**Status of the Claims**

Claims 27-28, and 33-34 are further withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

**Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of the Formula (I) , wherein:

**Y** is a valency bond; **Q** is H; and **n** is integer 1,  
or a composition comprising the said compound in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 14-26 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups, which are chemically recognized to differ in structure, function, and reactivity.

### ***Specification***

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

The Title is objected to for containing the term "New". This word should not be used to define an invention in a title, see MPEP § 606.

The Abstract is objected to because the sheet or sheets presenting the abstract may not include other parts of the application or other material, see MPEP § 608.01(b).

### ***Claim Objections***

Recitation of an intended to use or utility in the preamble which can otherwise stand alone is not considered a further limitation of the claim and therefore cannot impart patentability to a known composition of matter. See, *in re Spada*, 15 USPQ.2d 1655 (Fed. Cir. 1990).

Claims 19-24 are objected to under 37CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 14-26 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "a disease which can be favorably influenced by PARP inhibition and/or scavenging oxidative stress," is not described in the original disclosure to show which specific disease applicants possess invention relates to. The specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. *In re Gardner*, 166 USPQ 138 (CCPA 1970).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1626

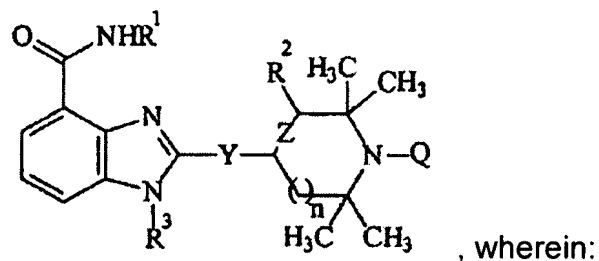
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-26 are rejected under 35 U.S.C. 103 (a) as unpatentable over *U.S.*

*Patent No. 6,448,271* by Lubisch et al. (the '271 patent).

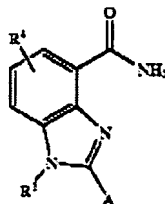
Applicant's claims relate to a compound of the Formula (I)



Y is a valency bond; Q is H; and n is integer 1;

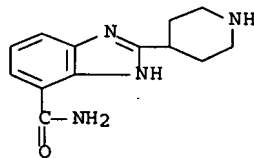
or a composition comprising the said compound in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)



The '271 patent disclose a class of compounds

used as PARP



inhibitor. More specifically, the compound (CAS RN 27269-49-8) was disclosed as a PARP inhibitor.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '271 patent and the instantly claimed compounds, is that the reference teaches the specific compound having piperidine bonded to the 2-position on the benzimidazole, but that compound does not have methyl groups substituted at 2- and 6-positions. However, the '271 patent claim 3 specifically define that A may be piperidine and substituted with C<sub>1</sub>-C<sub>4</sub>alkyl.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compounds *prima facie* obvious over the prior art compounds disclosed by the '271 patent, because the difference between prior art teaching and the instantly claimed compounds is -CH<sub>3</sub> substituted piperidine v.s. the -H substituted piperidine, which was suggested by the '271 patent as being C<sub>1</sub>-C<sub>4</sub>-alkyl group of "R<sup>3</sup>" for the same utility PARP inhibitor. The motivation to modify on the prior art reference is suggested by the teaching in Claim 3 of the prior art reference, and structurally similar compounds will have similar pharmaceutical activity with reasonable chance of success. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.



Art Unit: 1626

**Conclusion**

- Specification is objected to.
- Claims 14-26 are objected to.
- Claims 14-26 are rejected.

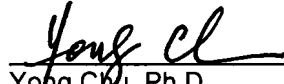
**Telephone Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.

The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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